CDS Connect Maintenance and Update

Final Report
(Year 4 of CDS Connect)





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Disclaimer of Conflict of Interest

None of the investigators has any affiliations or financial involvement that conflict with the material presented in this report.

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- Clinical Decision Support (CDS) Connect Work Group members
- CDS Connect Subcontractor Danny Van Leeuwen
- MITRE CDS Connect Project Team
- Health Level Seven, HL7®, and FHIR®

Executive Summary

AHRQ launched the Clinical Decision Support (CDS) Connect project in 2016 as part of its CDS initiative to put into practice patient-centered outcomes research (PCOR) findings, with focus on the topics, questions, and outcomes most important to patients and those who care for them. The first 3 years of the project included development and testing of the tools included in the CDS Connect platform. The fourth year of the CDS Connect project¹ focused on maintenance and updates to ensure that the tools are shareable, standards-based, publicly available, and patient centered. This annual report documents the project's accomplishments over the fourth year, organized into four task areas: Task Management, Trust Framework, Standards Conformance, and Outreach.

Task Management (manage project resources)

To meet the needs of the new maintenance and update phase, project leadership changed to provide expertise in program evaluation to support refinement of processes and an increased focus on growth and use.

In addition, new staff with expertise in user experience and engagement joined the CDS Connect project team (hereafter "the team") to promote the adoption and implementation of CDS Connect's offerings.

Trust Framework (prioritize activities based on promotion of trust)

To foster trust in CDS Connect, the team engaged with end users and other stakeholders to identify and prioritize updates. The team's analysis of stakeholder feedback resulted in a framework focused on two primary themes for CDS Connect updates:

- 1. Validate and update artifacts, as needed, to ensure that they reflect the most recent evidence-based clinical practice.
- 2. Update artifacts already in the Repository to ensure compliance with applicable health information technology (IT) standards.

Standards Conformance (ensure tools adhere to standards and are innovative)

CDS Connect tools and artifacts are more likely to be used if they adhere to existing, widely accepted standards and include useful innovations for end users. Accordingly, during this period of maintenance and update, the team introduced the following improvements based on the selected themes in Trust Framework task:

1. Implemented a process to review and update, as needed, all CDS artifacts in the CDS Connect Repository.

¹ The CDS Connect Maintenance and Update task order is in its first year, while the Health FFRDC's overall support to AHRQ for the CDS Connect project is in year 4, as referenced throughout this Final Report.

- 2. Applied Clinical Practice Guidelines (CPG)-on-Fast Healthcare Interoperability Resources (FHIR®) to the Repository and CDS Authoring Tool to align CDS Connect's tools and promote ease of implementation in the CDS community.
- 3. Upgraded software to FHIR Reference 4 (R4) to encourage innovative use.
- 4. Added a lessons learned series to the Work Group- 130+ CDS community members who provide diverse perspectives and help the team identify and prioritize key features and capabilities for CDS Connect
- 5. Refreshed the content across the CDS Connect website to accurately reflect the maturity of CDS Connect (e.g., using past tense for completed items as opposed to future tense).
- 6. Improved accessibility across all CDS Connect resources for persons with disabilities through broader application of standards established to support Section 508 accessibility requirements.

Aided by these improvements, members of the CDS community repurposed the CDS Authoring Tool to develop a prototype drug-drug interaction alerting system and query form while others built on the <u>Factors to Consider in Managing Chronic Pain: A Pain Management Summary</u> artifact.

Outreach (engage with the CDS community)

To promote adoption of CDS Connect and increase usability, it is important to engage with the CDS community through various mechanisms. These mechanisms may include face-to-face or virtual interactions with the CDS community (e.g., conference attendance) as well as "push" and "pull" methods of disseminating and gathering information to or from stakeholders (e.g., video, podcasts, and feedback collection). During the maintenance and update period, the team engaged with the CDS community in the following ways:

- 1. Traveled to participate in two conferences in the first half of the year, and then following onset of the COVID-19 pandemic, participated in a third conference virtually.
- 2. Created a short video for the CDS Connect welcome page to promote the use of standards and pilot testing in CDS.
- 3. Participated in a podcast, *CDS. Listen, Learn, Informed Choice.*, to discuss the importance of patient-centered CDS design and implementation.

The improvements to CDS Connect and deeper engagement with its stakeholders have established a foundation for ongoing success.

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1. Introduction

Clinicians must incorporate an unending stream of research findings, clinical practice guidelines, and best practices into daily practice. The Agency for Healthcare Research and Quality (AHRQ) helps clinicians and their teams to advance research findings into real-world practice through technical products such as clinical decision support (CDS). Since 2016, as part of AHRQ's patient-centered outcomes research (PCOR) CDS Initiative, the CDS Connect project has developed publicly available infrastructure for sharing interoperable, standards-based CDS. The resources available in the CDS Connect platform include:

- <u>Authoring Tool</u>: A tool for developing open source software for building CDS artifacts
- Repository: A platform for managing and sharing CDS artifacts, including artifacts developed by The MITRE Corporation (MITRE) and by others (e.g., Centers for Disease Control and Prevention [CDC] and Veterans Health Administration)
- Prototype Tools: Tools for testing and integrating CDS into health systems
- Work Group (WG): A group of CDS community members who provide diverse
 perspectives and help the team identify and prioritize key features and capabilities for
 CDS Connect
- **Pilots:** Proof-of-concept demonstrations based on CDS artifact use cases and testing in live, clinical/production settings (pilot reports are available)

Following initial development and proof-of-concept in the first 3 years of this project, CDS Connect began its next phase in year 4: maintaining innovation in the tools, updating tools based on current standards, and building awareness and use in the CDS community. <u>Final reports</u> from prior project years are available on CDS Connect.

1.1 Background

In 2016, AHRQ contracted with the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare Federally Funded Research and Development Center (the Health FFRDC), operated by MITRE,² to launch an effort promoting the dissemination and implementation of PCOR findings (as shown in Figure 1).

1

² The MITRE Corporation is "the Health FFRDC Operator."



Figure 1. AHRQ's PCOR CDS Initiative

In the 3 years that followed, the Health FFRDC team created and tested the components of CDS Connect: a repository of CDS artifacts, an authoring tool for creation of CDS, and prototype development tools for testing and integrating CDS into health systems. The success of CDS Connect was evidenced by community recognition, continued use of CDS artifacts, and evolving partnerships. In year 4, the initiative entered a new phase, with a focus on sustaining and updating to deepen end-user trust in CDS Connect among healthcare providers and expand use of the many artifacts available in the Repository.

1.2 CDS Connect Project Tasks

This year the team focused on four task areas:

- **Task Management:** Ensure effective project operations, including staffing, budgeting, invoicing, delivery, quality assurance, and related activities.
- Trust Framework: Identify opportunities to improve CDS Connect and increase trust in a CDS ecosystem by building on the Trust Framework set forth in the 2018 Patient-Centered CDS Learning Network white paper, "Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts."
- **Standards Conformance:** Maintain and update CDS Connect to meet stakeholder needs and adhere to industry CDS standards.
- Outreach: Engage with and learn from stakeholders about how to improve CDS Connect, including meetings, demonstrations, presentations at conferences, participation in WG meetings, and other activities.

1.3 CDS Connect Year 4 Milestones and Accomplishments

Key milestones and accomplishments in year 4 span the CDS Connect platform:

- CDS Connect Repository
 - o Improved usability (metadata tool tips, enhanced artifact knowledge-level graphic)
 - Updated to adhere to CPG-on-FHIR
 - o Redesigned user accounts for a single sign-in page
 - o Reviewed and updated process for new and existing artifact contributions
 - o Fixed bugs (e.g., NULL values and PATCH request)
- Authoring Tool
 - Updated to align with CPG-on-FHIR
 - o Updated tool and user guide to comply with Section 508 accessibility requirements
 - Fixed bugs (e.g., rendering issue, redirect link, International Classification of Diseases-10 [ICD-10] Uniform Resource Locator [URL] in code selector)

Prototype Tools

- Tested for compliance with FHIR Draft Standard for Trial Use 2 (DSTU2)/Standard for Trial Use 3 (STU3) resource and FHIR R4
- o Implemented backward-compatible Clinical Quality Language (CQL)
- Updated code systems
 - Aligned CQL services with CDS Hooks v1.0
 - Updated Pain Management Summary app, to include FHIR R4 support, Section 508 accessibility compliance, and maintenance improvements
 - o Updated tools and user guide to comply with Section 508 accessibility requirements

CDS Artifacts

- Established a review and update process, including application to existing contributions, development of Terms and Conditions, and formalization of the governance framework
- Updated all AHRQ/MITRE CDS artifacts, including review of evidence, metadata, and delivery of Section 508-accessible implementation guides
- o Reviewed new CDS artifact submissions

Work Group

 Invited presentations from external groups about their use of CDS Connect tools and resources to engage with the user community and promote the sharing of real-world experiences

Outreach

- Participated in Patient-Centered CDS Learning Network (PCCDS-LN) conference and Codeathon
- Presented live demonstration of CDS Connect at American Medical Informatics Association (AMIA) conference
- Presented virtual poster at Mobilizing Computable Biomedical Knowledge (MCBK) conference
- Sent periodic "What's New" email announcements to highlight enhancements in CDS
 Connect and invite users to learn more
- Produced CDS Connect video, <u>Improving the quality of healthcare delivery using</u>
 <u>standards-based Clinical Decision Support</u>, to promote the use of standards and pilot testing in CDS
- Participated in a podcast episode <u>CDS. Listen, Learn, Informed Choice</u>. as part of a CDS podcast series focused on patient-centered CDS design and implementation

2. Task Reports

Stakeholders rely on CDS Connect for its interoperable tools and resources, and they expect the content will adhere to clinical and technical standards. The team made key updates to CDS Connect's underlying technologies and knowledge resources to ensure the system is well maintained and innovative. These updates require specialized testing protocols and intimate knowledge of resources developed by the CDS Connect project. The team's work in year 4 executed on these requirements.

2.1 Task Management

The CDS Connect project team consists of a Project Leader, Deputy Project Leader, Technical Lead, Clinical Lead, and Task Leads. To meet the needs of the new maintenance and update phase, team leadership changed to provide expertise in program evaluation to support refinement of processes and an increased focus on growth and use. This change reflected the shift away from the team's development of CDS artifacts and toward maintaining and updating CDS Connect for maximum growth and use by the CDS community. The team also continued working with a patient/caregiver activist, Danny van Leeuwen of HealthHats, who provides a unique perspective in the continued development of CDS Connect.

In addition, new staff with expertise in code development and user experience and engagement joined the team to promote adoption and implementation of CDS Connect's resources. The expanded team achieved faster development cycles (e.g., the implementation of FHIR R4 with the Pain Management Summary application to meet CDS community requests), with added features to encourage continuous interaction with CDS Connect (e.g., "What's New?" with CDS Connect content in the monthly WG materials and email announcement).

The team completed 24 2-week sprints, or development cycles, throughout the project year. In addition, the team met regularly to consider, select, develop, test, and implement ideas to maintain and enhance CDS Connect. Among these ideas were refreshing the text on the CDS Connect site, redesigning how users sign in, and pivoting outreach plans in response to the COVID-19 pandemic. The team also regularly monitored relevant environmental factors (e.g., analyzing Food and Drug Administration rules on CDS and Facebook's "personalized health" app) to maintain situational awareness and flag potential impacts on the CDS community.

2.2 Trust Framework

In 2018, the PCCDS-LN produced a white paper entitled <u>Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts</u>. The recommendations in this white paper included a "Trust Framework" for supporting a trustworthy, knowledge-sharing CDS platform like CDS Connect. Although CDS Connect has already incorporated several of those recommendations, many of the white paper's recommendations had not yet been implemented.

During year 4, the team continued with improvements to CDS Connect to increase trust in the CDS ecosystem in accordance with the Trust Framework recommendations. The team took a systematic approach to prioritizing and implementing these recommendations. First, the team analyzed the white paper that presented the Trust Framework recommendations. That analysis included a review of the trust attributes, recommendations, and industry standards in the paper. It also included a gap analysis that compared the CDS Connect functionality in place at the end of year 3 against the Trust Framework recommendations. Second, the team identified the feasibility of updates, relevance to other AHRQ CDS initiatives, and which stakeholders endorsed an update (e.g., AHRQ, CDS Connect WG, and others identified by AHRQ). Third, the team developed a ranking and weighting scheme for the prioritization criteria. Lastly, the team developed a rubric and evaluation tool to objectively evaluate and prioritize the updates to CDS Connect. The team used the evaluation tool to assess the trustworthiness of potential updates.

This approach ensured the team's good stewardship of project resources by focusing on the updates that would provide greatest gains in stakeholder trust. The team's approach also leveraged inputs from the CDS community, respecting their voices and giving weight to the updates they felt would most benefit CDS Connect and enhance stakeholder trust.

Based on this systematic approach, the team identified two primary strategic themes for CDS Connect maintenance and update activities to increase trust in the CDS ecosystem:

- 1. **Ensure artifacts are current:** Update/validate artifacts to ensure that they reflect the most recent evidence-based clinical practice
- 2. Enhance artifacts to comply with standards: Update artifacts already in the Repository to ensure compliance with applicable health information technology (IT) standards

These themes bounded the scope of updates prioritized for CDS Connect during year 4 and guided sprint planning and agile decision making during this project year. Ultimately, the team used the rubric to assess more than 200 potential updates to CDS Connect. The specific prioritized enhancements included, but were not limited to:

- 1. Upgrading software to FHIR R4
- 2. Aligning the Authoring Tool and Repository to CPG-on-FHIR
- 3. Developing a process to update and review artifacts

The team completed 80 percent (12 of the 15) high-priority tasks, 55 percent of the lower-priority tasks (29 of the 53), as well as ad hoc items from the backlog of candidate enhancements. The team selected ad hoc items based on late-breaking project needs (e.g., updating website content) and staff availability.

The team's efforts to apply the Trust Framework recommendations to CDS Connect produced several positive outcomes. First, the team generated an organized list of potential updates to CDS Connect that could be rapidly prioritized using the evaluation tools. This approach helped avoid lags between completion of updates and the start of new updates. Second, by leveraging CDS community input in prioritization of CDS Connect updates (e.g., CDS artifact maintenance), the team respected stakeholder voices, which should foster greater trust in the CDS environment. This holistic approach to prioritizing CDS Connect updates is scalable for application to future project years to increase trust across the community and develop useful roadmaps to guide implementation.

2.3 Standards Conformance

This task centered on ensuring that CDS Connect components and processes continue to meet stakeholder needs and adhere to industry standards (especially, HL7®). Guided by priorities established with the <u>Trust Framework</u>, the team developed and delivered enhancements across all components of CDS Connect: the Repository, the CDS Authoring Tool, open source tools, CDS artifacts, and the WG.

The team made site usability enhancements that impact all components of CDS Connect. First, the team updated most of the informational pages on the CDS Connect site, some of which were originally written during year 1 or year 2 of the project. Each page was thoroughly reviewed and then revised after consultation with the appropriate stakeholders, including the CDS Connect project team patient/caregiver activist.

Second, the team revised the buttons on the CDS Connect site that allow visitors to contact the CDS Connect team for various reasons (e.g., join the WG, ask a question). These buttons previously appeared on two pages, Welcome to CDS Connect, and About CDS Connect. This original placement posed a usability issue because it required visitors to remember which pages included buttons. Most significantly, these buttons—including the button to join the WG—did not appear on the WG page. This issue was resolved by placing the buttons at the bottom of most pages on the CDS Connect site, including the WG page. In addition, the text for each button was revised to clarify its functionality.

Third, the team enhanced the accessibility of CDS Connect resources for persons with disabilities. Section 508 of the Rehabilitation Act, 29 U.S.C. 794d, establishes specifications for how content can be made accessible for people with visual or auditory challenges. The team made accessibility improvements to documents posted on the CDS Connect website and to artifacts in the Repository, including the Pain Management Summary App, the CDS Authoring Tool, and the prototype tools.

Lastly, the team converted CDS Connect systems documentation from a standard Word document to a "living" document in Confluence, which is more typical of a technical platform like CDS Connect. Maintaining the systems information in Confluence allows automatic tracking of changes and an easy-to-use linked format for quickly viewing technical details about CDS Connect.

The following subsections address specific enhancements to each component of CDS Connect.

2.3.1 Repository

The CDS Connect Repository was the first prototype tool released by the CDS Connect team. The Repository hosts structured, interoperable CDS expressions—known as CDS artifacts—that support clinician and patient decision making. The CDS artifacts on the Repository include contributions developed by the team, as well as those from trusted third parties. The goal of the Repository is to demonstrate how to incorporate evidence-based research more rapidly into clinical practice through interoperable CDS.

In year 1 of the development project, the team developed and delivered initial (alpha) and second (beta) versions of the Repository to AHRQ. For more information on year 1, please see the <u>final</u> <u>report</u> from that year.

Year 2 saw the release of the third (production) version of the Repository, which was the first version publicly accessible on the Internet. For more information on year 2, please see the <u>final</u> report from that year.

In year 3 of the project, the team made additional enhancements to the production version of the Repository. The final report from that year provides more information.

Year 4 began a new phase that emphasizes long-term maintenance and sustainability of the Repository. During year 4, the team updated and enhanced the Repository to better align with the

most recent CDS-related standards. The enhancements improved the user experience for Repository contributors and consumers. The following sections describe these enhancements.

2.3.1.1 Artifact Schema Update

Since year 1 of the project, there have been advances in the healthcare IT standards that can be used to describe CDS. In 2020, the first version of the FHIR Clinical Guidelines Implementation Guide (IG) was released as a standard for trial use. The FHIR Clinical Guidelines IG (a.k.a. the CPG-on-FHIR) was created as part of the CDC's Adapting Clinical Guidelines for the Digital Age initiative. Its purpose is to support "the development of standards-based computable representations of the content of clinical care guidelines" (http://build.fhir.org/ig/HL7/cqf-recommendations/index.html#intro). The team determined early in year 4 through coordination with the CDS Connect WG and CDS community that CDS Connect should align its tools with CPG-on-FHIR where feasible.

At the beginning of year 4, the team compared the CDS Connect artifact schema with the metadata defined in the CPG-on-FHIR IG (which builds from the FHIR Clinical Reasoning Module). Many alignments and similarities were documented, as were opportunities for harmonization. The team drafted a proposal to align the schema for artifacts on CDS Connect with CPG-on-FHIR. The proposal was reviewed with the CDS Connect WG. External feedback on the proposal was incorporated into a detailed design blueprint or "mockup," as shown in Figure 2. The goal of this design is to make it easier for users to contribute and consume CDS artifacts on the Repository.

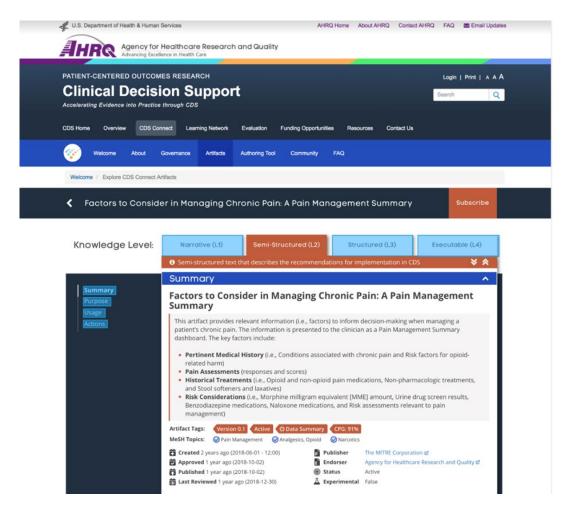


Figure 2. Image of Initial Design Mockup for New Artifact Schema

The new artifact schema necessitated changes to the Repository software.³ The team updated the database layer and the presentation layer of the Repository software to support the new schema design. This dual update to both the database and presentation layers was necessary because the design impacts how CDS artifact metadata are stored (database layer) and displayed to users (presentation layer). The team first prototyped and then reviewed the new schema with the CDS Connect WG in June 2020. Based on the WG's feedback, the team revised and further developed the new schema. At the time of the publication of this report, the technical work on these updates is complete. The team is now implementing a data migration strategy for converting existing artifacts in the Repository to the new format. Once all current artifacts in the Repository are migrated, the new schema will be deployed to the public.

2.3.1.2 Usability Improvements

Several public-facing aspects of the Repository were improved or refined. The team held discussions with external CDS artifact contributors and consumers who recommended

³ The repository software uses the <u>Drupal</u> content management system.

simplifying the multiple types of metadata date fields available for each artifact. Although this feedback will be resolved in the long term by the new CPG-on-FHIR aligned schema, a near-term solution was needed for the dates associated with CDS artifacts published on the Repository.

Currently, five separate dates can be associated with a single artifact; however, few CDS artifacts published on the Repository populate all five date fields. Most populate at least the Creation Date field, which is featured prominently next to each artifact entry,⁴ as shown in Figure 3. Featuring only the Creation Date for each artifact can make it appear that even recently updated artifacts are "old."



Figure 3. Illustration of Artifact Date Issue

The near-term solution to this issue was to update the Artifact Discovery page to show three dates beneath each artifact entry: the Creation Date, the Reviewed Date, and the Approval Date. Not every artifact has all these date fields populated—only those that are populated by the artifact authors show up on the Artifact Discovery page. The most recent of these three date fields is now prominently featured next to each artifact entry.⁵

The team also added informational <u>tooltips</u> for each metadata and artifact field to provide additional context without cluttering the display. These improvements will continue in the new artifact schema.

Another artifact metadata field that caused some confusion for users was the Knowledge Level field. The knowledge level of a CDS can take on one of four values, as described by Boxwala et

⁴ This update was implemented as part of the Artifact Discovery design in year 3.

⁵ This solution is accessible on the Artifact Discovery page.

<u>al.</u>—Level 1: Narrative, Level 2: Semi-structured, Level 3: Structured, or Level 4: Executable. User and stakeholder feedback suggested that the display of knowledge levels on the Repository was unclear. Like the date fields, this issue will ultimately be resolved via the new artifact schema design. In the short term, however, the solution was to provide additional context via a modal window pop-up shown in the example in Figure 4. When a user clicks on the knowledge-level graphic for an artifact, the modal window appears with definitions for each level, which were not provided in the original display.

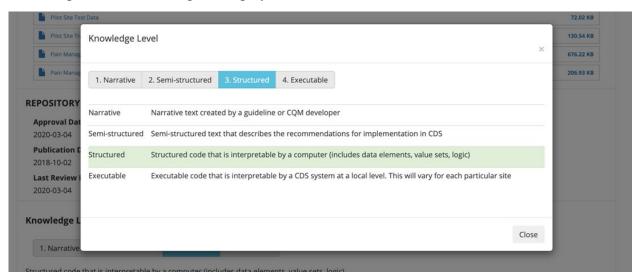


Figure 4. Knowledge-Level Modal Window Provides Additional Context to Users

2.3.1.3 General System Improvements

The team made many general system improvements to the Repository during year 4. The team updated the CDS Connect Repository Application Programming Interface (API)⁶ to improve robustness and resolve an issue with programmatically updating existing artifacts⁷. The team also worked with AHRQ IT to improve the Repository's automated email system to ensure that emails sent on behalf of the project appear more trustworthy⁸ to email servers and thus are less likely diverted to a person's junk or spam mail folder. This enhancement is key as the project continues to expand communications with its user base.

The team updated the Repository to ensure that security patches and bug fixes released for Drupal⁹ were applied in a timely manner. The Repository uses Drupal Version 8, which operates

⁶ The API was expanded and released as open source during year 3.

⁷ The API issue involved HTTP PATCH requests when modifying existing artifacts in the Repository. When PATCH requests contained incomplete bodies, the Repository would overwrite empty fields with NULL values. This issue was resolved by having the Repository API code set more sensible default values when handling incoming requests with incomplete bodies.

⁸ This work involved ensuring outgoing email headers contained consistent information as well as a valid DKIM (Domain Keys Identified Mail) signature.

⁹ The Repository is based on Drupal as the underlying CMS.

on a semiannual minor version release cycle. Because each minor release for Drupal receives security support for 1 year, it is important that the Repository stay current. As of the date of this report, the Repository is on the long-term support release for Drupal 8.

2.3.2 Authoring Tool

In year 1 of the CDS Connect project, the team designed and built the CDS Authoring Tool, a user-friendly web application for creating standards-based CDS logic using HL7 CQL and HL7 FHIR. The team spent years 2 and 3 improving the CDS Authoring Tool based on project requirements and user feedback. By the end of year 3, the CDS Authoring Tool supported the following features:

- Logging in with a user account to manage a personal set of CDS logic artifacts
- **Authoring** CDS logic using inclusion and exclusion criteria, sub-populations, and conditional recommendations
- **Integrating** with the National Library of Medicine's Value Set Authority Center (VSAC) to find and select value sets as well as to validate individual codes
- **Defining** "base elements" that can be specified once and used multiple times throughout the artifact
- Importing externally authored CQL to support constructs not expressible in the CDS Authoring Tool
- **Specifying** run-time parameters to allow implementers to change the behavior of CQL logic at run-time
- Annotating CDS elements with human-readable comments
- **Testing** authored logic using synthetic data to verify its correctness
- **Exporting** valid CQL using the FHIR Draft Standard for Trial Use 2 or FHIR Standard for Trial Use 3 data models

The CDS Authoring Tool is provided under an open source Apache 2.0 license and hosted in an AHRQ production environment. Going into year 4, the CDS Authoring Tool had 188 registered users, with 367 registered users as of the writing of this report.

2.3.2.1 Authoring Tool Enhancements

During year 4, the team focused on expanding support of health IT standards, improving usability of the tool, and supporting accessibility.

2.3.2.1.1 FHIR R4

While many health IT vendors currently support HL7 FHIR DSTU2 in clinical environments, the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT

<u>Certification</u> final rule calls for the implementation and support of HL7 FHIR R4. The team has updated the CDS Authoring Tool to support FHIR R4 while maintaining backward compatibility with FHIR DSTU2 and STU3.

As shown in Figure 5, authors can now download their artifacts using FHIR R4. The downloaded CQL libraries will properly reference the FHIR R4 data model, query for FHIR R4 resources, and use the appropriate FHIR R4-based dependency libraries.

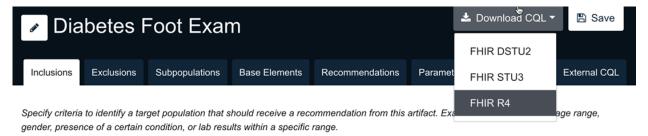


Figure 5. Downloading a CDS Artifact Using the FHIR R4 Data Model

In addition, authors can now upload external CQL libraries that use the FHIR R4 data model. When they do, the authored library will be locked into the FHIR R4 format, and authors will no longer be able to export the library as FHIR DSTU2 or STU3.

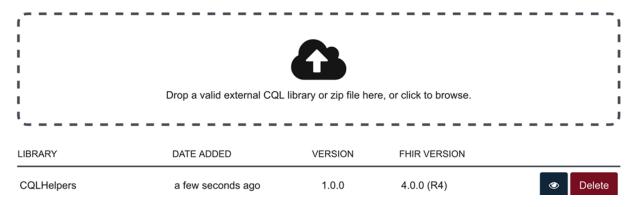


Figure 6. An Uploaded External CQL Library Using FHIR R4

The CDS Authoring Tool also allows authors to upload synthetic test patients in the FHIR R4 format. Since FHIR does not require data to declare its version of FHIR, authors must now indicate to which version of FHIR the synthetic data conforms. Previous versions of the CDS Authoring Tool could detect this based on the form of the data itself, but this is not feasible with FHIR R4.

NAME	BIRTH DATE	GENDER	VERSION	LAST UPDATED	
Diabetic Minor	2008-09-18	male	R4	a month ago	Delete
Eli Excluded	2000-02-16	male	DSTU2	4 months ago	Delete

Figure 7. Synthetic Test Patients Using FHIR R4 and FHIR5 DSTU2

Given that FHIR R4 is the new FHIR version of choice, the team aligned the CDS Authoring Tool user interface with FHIR R4 terminology. This resulted in one minor change: what was formerly referred to as "Medication Order" is now a "Medication Request."

2.3.2.1.2 FHIR Clinical Guidelines

One important way in which the CDS Authoring Tool now aligns with CPG-on-FHIR is by allowing authors to specify CPG-on-FHIR metadata related to the CDS library they are authoring. Previous versions of the CDS Authoring Tool focused only on the authoring of CDS *logic*, but important metadata about the CDS itself could not be specified within the CDS Authoring Tool. Authors can now specify metadata defined in CPG-on-FHIR's CPGPublishableLibrary profile. This metadata includes fields such as status, publisher, purpose, and related artifacts. To encourage authors to provide this data, the CDS Authoring Tool provides a score indicating the completeness of the data based on recommended fields (as shown in Figure 8).



Figure 8. The CPG-on-FHIR-inspired Artifact Form

When the author has provided enough data, the download package for the artifact will contain a valid CPGPublishableLibrary instance in addition to the CQL logic libraries. This CPGPublishableLibrary instance will contain author-provided metadata and metadata that can be inferred from the CDS logic, such as data requirements.

The CPG-on-FHIR also provides recommendations for expressing CQL libraries. Although the CQL specification itself is lenient in many areas, the CPG-on-FHIR IG promotes consistency between CDS libraries by standardizing several components of authoring. Where possible, the CDS Authoring Tool promotes or enforces these authoring standards. For example, CPG-on-FHIR suggests that libraries use the <u>Apache APR versioning scheme</u>, which splits versions into major, minor, and patch components. While the CDS Authoring Tool does not require authors to use this versioning scheme, it will now notify authors (as shown in Figure 9) when they have provided a version number that does not match the recommended approach.



Figure 9. Example of a Non-Conformant Version Number

CPG-on-FHIR also specifies that value sets should be referenced using a Universal Resource Identifier (URI). Previous versions of the CDS Authoring Tool-referenced value sets used Object Identifiers (OID). The CDS Authoring Tool now uses URIs to identify value sets. For example, a value set previously identified using the OID "2.16.840.1.113883.3.464.1003.103.12.1001" is now identified using the URI

"https://cts.nlm.nih.gov/fhir/ValueSet/2.16.840.1.113883.3.464.1003.103.12.1001."

```
Diabetes-Foot-Exam.cql ×

Users > cmoesel > Downloads > diabetes_foot_exam_v0_0_1_cql(2) > Diabetes-Foot-Exam.cql

library "Diabetes-Foot-Exam" version '0.0.1'

using FHIR version '4.0.0'

include "FHIRHelpers" version '4.0.0' called FHIRHelpers

valueset "Diabetes VS": 'https://cts.nlm.nih.gov/fhir/ValueSet/2.16.840.1.113883.3.464.1003.103.12.1001'

valueset "Pulse Exam of Foot VS": 'https://cts.nlm.nih.gov/fhir/ValueSet/2.16.840.1.113883.3.464.1003.103.12.1015'
```

Figure 10. Exported CQL with URL Identifiers for Value Sets

In addition, CPG-on-FHIR defines a set of recommended options when translating CQL to the Expression Logical Model (ELM) format using open source tooling. In year 4, the team updated the CDS Authoring Tool to follow the CPG-on-FHIR recommendations when building the CQL and ELM download package for CDS artifacts.

Most of the remaining CQL authoring conventions covered in CPG-on-FHIR were already supported in the CDS Authoring Tool before year 4.

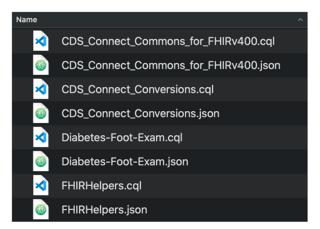
2.3.2.1.3 Consolidated CQL

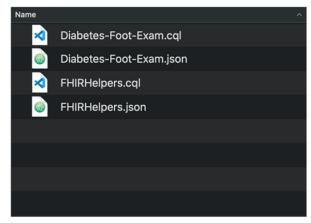
Initial versions of the CDS Authoring Tool exported each CDS artifact as a zip file containing a primary CQL library as well as several CDS Connect libraries on which it depended. Even though this approach is valid, there were some disadvantages:

- "Extra" Functions: The accompanying libraries were defined to work for all features of the CDS Authoring Tool but often contained functions that a given artifact might not need or use.
- **Potential for User Confusion:** The additional libraries and/or the inclusion of functions that are not relevant to their specific artifact could confuse users of the CDS Authoring Tool.

• Compatibility Issues: Artifacts exported from different versions of the CDS Authoring Tool might not be compatible with each other because they depend on different versions of the same common CDS Connect libraries.

To address these issues, in year 4 the team developed a new utility that can "consolidate" CQL from multiple libraries into a single library. Using this capability, the CDS Authoring Tool now exports a single primary library embedded with the common functions it uses. This utility produces an easier-to-understand CQL artifact that contains only logic that is directly relevant to the artifact itself.





Previous CQL Export Contents

Consolidated CQL Export Contents

Figure 11. Comparison of Previous and Consolidated CQL Exports

2.3.2.1.4 Usability

The team also focused on improving usability of the CDS Authoring Tool. Usability enhancements were based on feedback from users and usability experts inside and outside the team. A review of a representative sampling of usability enhancements implemented in year 4 shows the many improvements in the CDS Authoring Tool experience. For example, users can:

- Re-order recommendations, affecting how the recommendation logic flows
- Delete recommendations that are no longer applicable
- Add comments (a.k.a. annotations) to recommendations
- Remove rationale, subpopulation, and comments from recommendations
- Add comments (a.k.a. annotations) to groups
- Show or hide comments via a comment display button
- View appropriate labels for all fields, indicating their use
- Receive a warning when attempting to log in using an email address instead of their username

In addition, the CDS Authoring Tool User Guide was completely rewritten to guide users through the features of the CDS Authoring Tool.

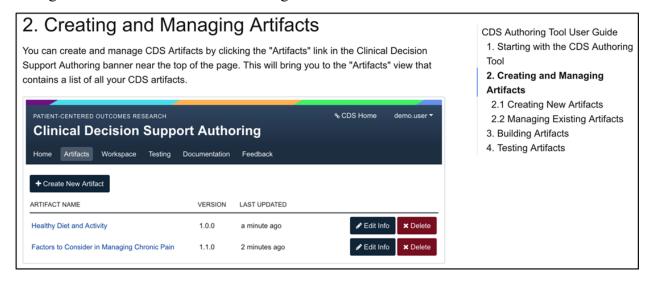


Figure 12. The CDS Authoring Tool User Guide

2.3.2.1.5 Accessibility

In year 4, the team worked to ensure accessibility of the CDS Authoring Tool according to Section 508 compliance standards. A subject matter expert addressed and identified various accessibility issues. These issues were remedied. The improvements included Mozilla Accessible Rich Internet Applications (ARIA) accessibility enhancements to the user experience when using screen readers such as Job Access With Speech (JAWS) and VoiceOver, color contrast improvements using the WebAIM Contrast Checker, navigation improvements such as adding skip links, and other minor stylistic changes to improve overall accessibility.

2.3.2.1.6 Maintainability

In planning for long-term sustainability, the team manages and improves the CDS Authoring Tool's maintenance efficiency. In year 4, the team upgraded the CDS Authoring Tool's primary front-end framework from React 15 to React 16. This upgrade allowed simplifying the code of the CDS Authoring Tool in some areas, improved overall performance, reduced the overall file size of the deployed application, and paved the way for future improvements. The team also made other incremental improvements to keep the code clean and maintainable.

2.3.2.1.7 Production Environment

In year 4, the team worked with AHRQ IT to migrate the CDS Authoring Tool production environment from Ubuntu 14 to Ubuntu 18. This upgrade improved the overall security of the CDS Authoring Tool platform without affecting the user experience. To ensure a fully secure environment, the team and AHRQ IT also upgraded the Ubuntu servers in the development and staging environments.

2.3.2.2 Open Source Use

In addition to hosting the CDS Authoring Tool, AHRQ provides the CDS Authoring Tool as open source software under an Apache 2.0 license on GitHub. In year 4, several organizations took advantage of this open source license to use the CDS Authoring Tool code in new and exciting ways, including:

- An AHRQ grantee repurposed the CDS Authoring Tool open source code to develop a prototype drug-drug interaction alerting system.
- Faculty at a medical school incorporated the CDS Authoring Tool into a CDS authoring platform using several other open source CDS tools as well.
- The team repurposed components of the CDS Authoring Tool to develop a "pathways builder" that allows authors to develop CQL-based clinical pathways for oncology.

2.3.3 Open Source Tools

The CDS Connect project has developed other open source tools over previous years. These include CQL Services, the CQL Testing Framework, and the Pain Management Summary Application.

2.3.3.1 CQL Services

CQL Services is an open source application that enables users to expose CQL-authored logic over custom and standards-based web services. In year 4, the team continued to provide enhancements and bug fixes to CQL Services in alignment with overall project goals.

2.3.3.2 CQL Services Enhancements

2.3.3.2.1 FHIR STU3 and R4

Because HL7 FHIR R4 is expected to grow in popularity and adoption, the team added support for HL7 FHIR R4 to CQL Services. CQL libraries authored using the FHIR R4 data model can be integrated with and exposed via CQL Services. To ensure support for all available FHIR versions, the team also added support for FHIR STU3.

2.3.3.2.2 CDS Hooks 1.0

CQL Services supports exposing CQL libraries using the HL7 CDS Hooks API. Previous versions of CQL Services were developed for a pre-1.0 version of CDS Hooks. In year 4, the team updated CQL Services to ensure it aligns with the now-official CDS Hooks 1.0 release. CQL Services still has limitations regarding CDS Hooks (e.g., only prefetch data are supported), but everything that CQL Services supports is now compliant with CDS Hooks 1.0.

2.3.3.2.3 URL-Based Value Sets

The CPG-on-FHIR specification suggests that CQL should always refer to value sets using their official URL identifiers. Previous versions of CQL Services supported only VSAC value sets identified using their OID. In year 4, the team updated CQL Services to support VSAC value sets defined using their official VSAC URL identifiers. This update allows CQL Services to better support artifacts that are CPG-on-FHIR-compliant.

2.3.3.3 CQL Testing Framework

The CQL Testing Framework is an open source library that allows developers to create and execute tests cases for CQL libraries. Unlike the testing feature in the CDS Authoring Tool, the CQL Testing Framework can work with any CQL (wherever it was developed) and can test actual against expected results. In year 4, the team continued to provide enhancements and bug fixes to the CQL Testing Framework.

2.3.3.4 CQL Testing Framework Enhancements

2.3.3.4.1 Support for All Resource Types

Prior versions of the CQL Testing Framework supported a small subset of FHIR data types and their properties. CQL developers who needed to test CQL using other data types had to manually add support to the CQL Testing Framework. In year 4, the team implemented a capability that allows the CQL Testing Framework to process the formal FHIR specification definitions and understand all the available data types and properties. With this capability, the CQL Testing Framework now supports every FHIR data type and property.

2.3.3.4.2 FHIR R4

The team added support for HL7 FHIR R4 to the CQL Testing Framework. This means that CQL libraries authored using the FHIR R4 data model can be tested using the framework (in addition to the existing support for FHIR DSTU2 and STU3).

2.3.3.4.3 URL-Based Value Sets

The CPG-on-FHIR specification suggests that CQL should always refer to value sets using their official URL identifiers. Previous versions of the CQL Testing Framework supported only VSAC value sets identified using their OID. In year 4, the team updated the CQL Testing Framework to support VSAC value sets defined using their official VSAC URL identifiers. This allows authors of CPG-on-FHIR-compliant CQL artifacts to use the CQL Testing Framework more easily.

2.3.3.5 Pain Management Summary Application

The Pain Management Summary Application is a Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR application that allows clinicians and patients to view all

individual patient data that might be relevant to managing that patient's pain. The Pain Management Summary application was developed and piloted in year 2 of CDS Connect. In year 4, several other organizations took an interest in the Pain Management Summary application. The team provided updates and enhancements to support these activities.

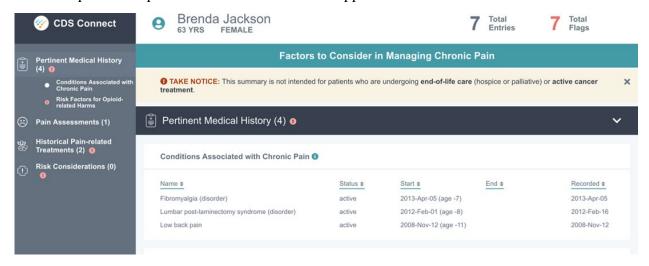


Figure 13. The Pain Management Summary Application

2.3.3.6 Pain Management Summary Application Enhancements

2.3.3.6.1 FHIR R4

As health IT products begin to adopt HL7 FHIR R4, SMART on FHIR applications should also support FHIR R4 to ensure compatibility. In year 4, the team developed a FHIR R4 representation of the Pain Management Summary's underlying CQL logic. The team also updated the application itself to support authentication, authorization, and querying of FHIR R4 servers. To maintain compatibility with the widest variety of health IT products, the team also retained support for FHIR DSTU2. When the latest version of the Pain Management Summary Application launches, it dynamically detects the version of FHIR in use and acts accordingly.

2.3.3.6.2 CQL Logic

In addition to updating the underlying CQL logic to support FHIR R4, the team updated the logic to use the most recent value sets and standards-based codes available.

2.3.3.6.3 Accessibility

Year 4 included ensuring accessibility to the Pain Management Summary application according to Section 508 compliance standards. A subject matter expert reviewed the application, and addressed and identified various accessibility issues. These issues were remedied. These improvements include Mozilla ARIA enhancements to the user experience when using screen readers such as JAWS and VoiceOver, color contrast improvements using the WebAIM Contrast Checker, navigation improvements such as adding skip links, and other minor stylistic changes.

Infrastructure Improvements

To better support adoption and modification by other organizations, the team improved the underlying components of the application itself. This included refactoring the application to use a popular library, "Create React App," and upgrading the FHIR client libraries to better support FHIR DSTU2 and R4 concurrently.

2.3.3.7 Open Source Use

The team is aware of three separate reuses of the Pain Management Summary application in year 4. In two cases, organizations have adopted and extended the Pain Management Summary application to provide additional pain-related data, including data from prescription drug monitoring programs. In the third case, an organization has reused the overall structure of the Pain Management Summary application but replaced all the pain-related content with content pertaining to COVID-19.

2.3.4 CDS Artifacts

The team reviewed and updated all CDS artifacts developed within the CDS Connect project (as described in Table 1). The team's criteria for considering updates included consideration of relevant research evidence, metadata, value sets or clinical concept, and documentation, as described in the FAQ *How do I maintain my contributed artifacts?*

Table 1. Annual Review and Update of CDS Connect Project Team Authored CDS Artifacts

CDS Artifacts ¹⁰	Evidence Updates	Metadata Updates	Value Set Updates	Documentation Updates
Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part One, Screening	No	Yes	Yes	No
Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part Two, Counseling	No	Yes	Yes	No
Aspirin Therapy for Primary Prevention of CVD and Colorectal Cancer	No	Yes	N/A	Yes, to meet Section 508 accessibility requirements
CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10- Year ASCVD Risk	No	Yes	Yes	No

Occupational Factors Impacting Diabetes is under consideration for update or retirement in coordination with the National Institute for Occupational Safety and Health.

CDS Artifacts ¹⁰	Evidence Updates	Metadata Updates	Value Set Updates	Documentation Updates
CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Shared Decision Making	No	Yes	N/A	Yes, to meet Section 508 accessibility requirements
CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Updated 10- Year ASCVD Risk	No	Yes	N/A	Yes, to meet Section 508 accessibility requirements
Factors to Consider in Managing Chronic Pain: A Pain Management Summary	Yes	Yes	Yes	Yes
Healthful Diet and Physical Activity for CVD Prevention in Adults With Cardiovascular Risk Factors	No	Yes	Yes	No
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) eCQM	Yes	Yes	Yes	Yes, to meet Section 508 accessibility requirements
Statin Use for the Primary Prevention of CVD in Adults: Clinician-Facing CDS Intervention	No	Yes	Yes	Yes, to meet Section 508 accessibility requirements
Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention	No	Yes	Yes	No

Beginning this project year, the team worked with the CDS community, including the WG, to review and update other artifacts contributed to the Repository outside of the team. This effort is a major accomplishment to maintaining trust in CDS Connect. As part of this process, the team revised the draft governance developed in prior years of CDS Connect. The team also developed Terms and Conditions (T&Cs) that delineate the expectations and roles in contributing to the Repository and incorporated these T&Cs into the account login process. Lastly, the team worked with artifact authors to review and update their CDS artifacts, including a review of their evidence, metadata, value sets, and documentation.

The team also worked with contributors providing new CDS artifacts to the Repository. Contributors included other Federal agencies, existing contributors, and individuals within medical systems. Activities included providing informational meetings to those asking to learn more about the contribution process, creating accounts and advising them on how to use the Repository, and reviewing submitted material ahead of publishing it to the CDS Connect Repository.

2.3.5 Work Group

The WG serves a critical function by providing diverse subject matter expertise to aid in the prioritization of CDS Connect development activities. The WG has engaged throughout key project phases, from consideration of high-level desired outcomes for CDS Connect to selection of optimal approaches for maintaining and updating CDS Connect. In year 4, the team worked with the WG moderator to maintain the CDS Connect WG, including but not limited to facilitating monthly virtual meetings, developing agendas and content, summarizing meetings through publicly available notes and presentation materials, and responding to questions from new and existing members.

The team works with the WG's 130-plus members to promote engagement from the diverse members, whose expertise ranges from clinicians to coders. After the first quarter of year 4, the team noticed a decline in WG meeting attendance and engagement (as noted in Lessons Learned in this report), a trend that began in year 3. To boost engagement, the team reorganized WG meetings to include presentations from WG members about their experiences using CDS Connect tools and resources. Five lessons learned presentations were shared in year 4. The team also reduced the length of the meeting from 90 to 60 minutes, shared the draft slide deck in advance, and highlighted specific feedback needed. During the meetings, the team focused on specific discussion questions with clear objectives and used the chat feature to invite greater participation. Attendance and participation increased noticeably immediately following these changes. It will be important to watch trends over time and solicit feedback on the changes from WG members.

The CDS Connect WG met 10 times during the reporting period (Oct 2019–Aug 2020). The WG meeting was canceled in November related to proximity to a major conference. Meetings averaged 30 WG members a month, and overall attendance ranged from 39 to 61 attendees. Seven guest speakers presented on lessons learned using CDS Connect artifacts:

- Translation of *C. difficile* Infection Treatment Clinical Pathway into Machine-readable and Shareable CDS
- Use of CDS Connect Authoring Tool in Academia
- CDS Usability: Mobilizing a Million Hearts
- FHIR-based CDS Sandbox
- Developing CDS Artifacts for Hypertension
- CDS Authoring Tool as a Unified Query Builder within the Clinical Environment
- Development of five CDS artifacts for the CDC

2.4 Outreach

During year 4, the team's outreach efforts concentrated on meeting with stakeholders to ensure that their needs were addressed during this maintenance and update phase of CDS Connect. Activities included:

- **Demonstrating** CDS Connect tools and functionalities
- Facilitating and participating in meetings between AHRQ and stakeholder groups (e.g., potential sustainer organizations, Federal partners, and grantees)
- Tracking stakeholder recommendations for consideration in future sprints
- Presenting at national research or developer conferences
- Participating in appropriate standards WG meetings (e.g., HL7).
- Building awareness and use of CDS Connect using varied platforms (e.g., email notifications and video)

The second half of year 4 outreach was shaped by the COVID-19 pandemic. Beginning in spring 2020, the team responded to work-from-home orders and cancellation of conferences or conversion to online-only meetings. These accommodations persisted for the remainder of the project year. For example, the team had planned to participate in person at the Healthcare Information and Management Systems Society (HIMSS) 2020, HL7 Connectathon, and the MCBK annual conference. At each of these events, the team expected to network with the CDS community and demonstrate CDS Connect tools and functionalities. HIMSS 2020 was canceled because of COVID-19 concerns, and the HL7 Connectathon and MCBK conference converted to a virtual format.

The team responded to COVID-19 by creating an alternative plan to deliver outreach to the CDS community through more diverse media or channels. The plan included, for example, development of the CDS Connect video *Improving the quality of healthcare delivery using standards-based Clinical Decision Support* that shared lessons learned from CDS Connect's experience conducting pilots in prior years. The goal of the video is to promote the use of standards and interoperability and build awareness of CDS Connect.

Ultimately, the team's alternative outreach plan succeeded in adapting the team's outreach and continued engagement with the CDS community during an unprecedented season that significantly challenged health safety for outreach activities. The alternative plan's effective use of resources made it possible to conduct parallel outreach efforts while development work continued at the same level of output.

2.4.1 Conferences

The team attended several conferences or events in project year 4, with the goal of identifying current trends and issues related to patient-centered CDS and gauging attendees' level of awareness and use of CDS Connect.

2.4.1.1 2019 Annual Conference of Patient-Centered CDS Learning Network

The team attended the PCCDS-LN Conference in Washington, DC on October 21, 2019. Several members of the CDS Connect WG participated as presenters and panelists at the conference, including but not limited to Maria Michaels (CDC), Blackford Middleton (Apervita), Barry Blumenfeld (RTI), Danny van Leeuwen (Health Hats), and Dr. Ken Kawamoto (University of Utah).

Notable themes and topics in presentations and discussions at the conference included:

- Leveraging CDS to enable informed decision making by clinicians and patients
- Differences between clinician and patient needs and uses for CDS (usability)
- Continued importance of trust in relation to CDS
- Unresolved questions of policy/liability as a potential impediment to progress
- The need for a guiding influence to set standards, establish best practices, and maintain an index of artifacts

The team also attended the concurrent PCCDS-LN Codeathon. At the Codeathon, developers demonstrated applications and conferred with company representatives, as well as government and non-profit attendees, about integrating their applications with other tools. Team members observed limited demonstrations of CDS applications in the Epic App Orchard and interacted with developers to assess awareness of CDS Connect. Some Codeathon participants were aware of CDS Connect, having used the Authoring Tool or by submitting artifacts to the Repository.

Many conference attendees were not yet aware of or familiar with CDS Connect; however, CDS Connect was mentioned often during the day's presentations. Dr. Richard D. Boyce (University of Pittsburgh School of Medicine, Center for Pharmaceutical Policy and Prescribing) discussed plans to start a 2-year project using CDS Connect. Jeremy Michel (Children's Hospital of Philadelphia, a CDS Connect WG member), shared that he had published two articles on CDS Connect and planned to publish an Attention Deficit Hyperactivity Disorder CDS module to the CDS Connect Repository.

2.4.1.2 2019 American Medical Informatics Association

In November 2019, members of the team participated in the AMIA Annual Symposium held in Washington, DC. On November 17, Dr. Edwin Lomotan shared CDS Connect's work on the Pain Management Summary application during a panel about leveraging CDS to address opioid misuse. On November 18, Dr. Lomotan and Shafa Al-Showk of AHRQ participated in a panel

that discussed the findings of a study that compared implementing shareable CDS (via CDS Connect) to implementing internally developed CDS. On November 19, Shafa Al-Showk and team member Chris Moesel demonstrated CDS Connect's open source tools, highlighting the CDS Authoring Tool, CQL Testing Framework, and CQL Services. The team's live demonstration at the symposium was entitled "Authoring and Integrating Interoperable Clinical Decision Support: CDS Connect Open Source Tools." The team showed how the CDS Authoring Tool can be used to develop standards-based CDS logic, as well as how to test and integrate that logic in clinical environments. On the same day, Chris Moesel and Kristen Valdes (CEO of b.well) discussed and demonstrated the CDS Connect 2019 pilot of consumer-facing CDS artifact at b.well.

The four sessions in which the team participated were well attended and evoked thought-provoking questions from attendees. Several other sessions also mentioned CDS Connect and/or its work. The general need for computable guidelines, as well as the importance of trust, were pervasive themes that emerged from many CDS-related sessions. The team also met with current and potential CDS Connect users and learned of some exciting uses of CDS Connect as a teaching tool in universities.

One of three submissions the team prepared for AMIA 2020, entitled "The New Digital Age of Clinical Decision Support Tools: Open-Source and Interoperable Approaches for Health Systems," was accepted. 11 Chris Moesel will serve as a panelist on this workshop and will provide a 30-minute review of open CDS standards and tools (including CDS Connect tools). The workshop will also feature Andrey Soares' CDS sandbox, which includes CDS Authoring Tool and CQL Services.

2.4.1.3 2020 Mobilizing Computable Biomedical Knowledge Annual Conference

The team originally submitted an in-person systems demonstration at MCBK; however, because of the pandemic, this was converted to a virtual technical poster presentation that occurred June 30 and July 1. The team and AHRQ jointly authored "CDS Connect—A Platform for Sharing and Authoring CDS Artifacts." The focus of the session was on the Repository and how to contribute CDS artifacts; the presentation touched on the CDS Authoring Tool and other tools that may help ease the contribution process. The team was also invited to present at a separate WG action session entitled "Technical Infrastructure for MCBK." Each session included a highly engaged audience and the team extended invitations for further followup to learn about or use CDS Connect. The audience expressed notable interest in the open source and standards-based tooling.

2.4.2 GitHub Metrics

Although GitHub only provides project metrics for the previous 2 weeks, the team developed a tool in May 2020 to collect project metrics daily to track them over time. Figure 14 and Figure

¹¹ Despite strong reviews, the first two submissions were not accepted.

15 display page views and clones, respectively, beginning May 2020 until August 2020. On GitHub, a "clone" represents when a user has downloaded the open source code to their system for local use and modification.

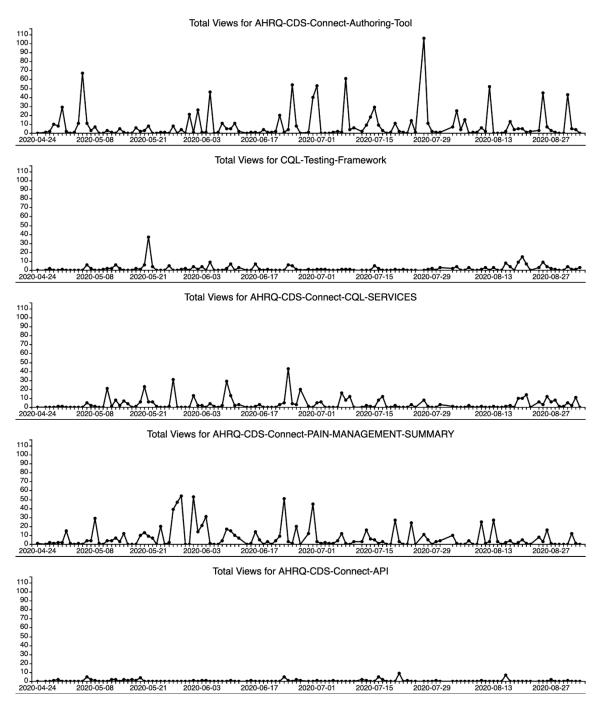


Figure 14. Total Views for AHRQ-CDS GitHub Repositories

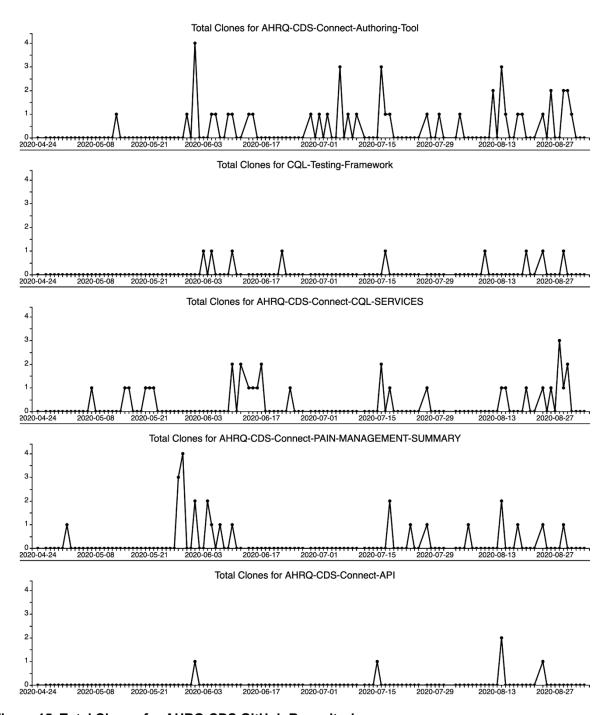


Figure 15. Total Clones for AHRQ-CDS GitHub Repositories

2.4.3 CDS Community

The team regularly engages with CDS community stakeholders beyond the CDS Connect WG. These engagements include existing contributors (e.g., Children's Hospital of Philadelphia); Federal partners (CMS [including Value Set WG]; CDC, National Institutes of Health National Center for Advancing Translational Sciences); non-profits (e.g., World Health Organization);

and other CDS meetings (e.g., Business Process Management + Health WG, Addressing Chronic Pain through Patient- and Clinician-facing CDS Webinar).

In May 2020, the team began sending regular updates by email to WG members and others who had signed up through the CDS Connect website. The email updates summarized recent development efforts reported during the WG meeting and were intended to help drive traffic to the CDS Connect site. The initial email update went to 600-plus unique email addresses and generated followup interest. After receiving this email, CMS integrated the email and its content into their offerings for quality measure developers on the eCQI Resource Center site.

To provide a patient perspective, Danny van Leeuwen (HealthHats) continued to serve as a patient/caregiver activist and advocate, working closely with CDS Connect. He participates regularly in the CDS Connect WG and provides critical input on public-facing outputs (e.g., suggested improvements to plain language and readability of the CDS Connect). He also developed a collaborative conference submission to showcase the patient perspective in CDS. As part of the alternative plan for outreach, the team coordinated with Mr. van Leeuwen to shape a CDS podcast series. Mr. van Leeuwen included existing CDS episodes on his HealthHats Podcast and recorded new CDS episodes as part of a collection available on his website. Members of the team participated in the CDS. Listen, Learn, Informed Choice. episode included in the collection and worked with Mr. van Leeuwen to promote the series via various channels.

3. Lessons Learned

During project year 4, the team observed the following lessons learned that may be useful for CDS projects and the broader CDS community.

1. Growing Trust in CDS Connect

a. A framework to prioritize enhancements will be helpful as CDS Connect grows. As the scope of tools, artifacts, and users of CDS Connect expands, so might the number of potential enhancements that could add value for various components or user bases. The systematic approach the team applied to prioritize updates for implementation is a rigorous, repeatable process that can be used in the future to reassess strategic priorities and criteria or to refresh the list of prioritized updates. This method systematically solicits input from multiple stakeholders, which is an enhancement over previous approaches and helps AHRQ establish a rationale for decision making as it engages with leadership and considers transition options.

2. Maintaining open-source, standards-based offerings

a. Aligning with standards creates an opportunity for efficient, collaborative development. By maintaining situational awareness of emerging standards, the team recognized value in the CPG-on-FHIR IG. By aligning the Repository and Authoring Tool with this standard, CDS Connect benefited from the decades of experience and hundreds of hours of work invested by the standards community. In addition, because

- FHIR Clinical Guidelines is an emerging standard, CDS Connect could help inform and improve the FHIR Clinical Guidelines IG as it was developed.
- b. Design CDS applications for extension and reuse by aligning with standards and providing documentation on development. In year 4, the Pain Management Summary application was extended by multiple teams and was even reused as a framework in an entirely different context: COVID-19 symptom management. To support extension and reuse, application developers should provide detailed build documentation, simplify the build and maintenance processes as much as possible, use approaches that allow for additional flexibility (such as multiple FHIR versions), organize code to separate concerns such as logic and user interface, and provide utilities to make it easy to update CQL logic and/or value sets.

3. Promoting CDS Connect through engagement with the CDS community

- a. Inviting lessons learned from the user community creates a valuable forum for directly gathering feedback. The varied, real-world experience and insight of WG members provided major value to the CDS Connect project efforts. Ensuring that systems and resources produced by CDS Connect are informed by stakeholder feedback amplifies the usefulness, usability, and longevity of the systems.
- b. Recognize when an adaptation is necessary and be flexible to pivot from the status quo. The team benefited from an agile, flexible approach to respond to environmental trends and conditions. For instance, the team leveraged nontraditional communication channels (e.g., video and podcasts) to build awareness of CDS Connect during the pandemic. In addition, after observing a declining pattern in WG attendance and participation, the team modified meeting content (i.e., adding a lessons learned series) and logistics (i.e., shortened meeting, advance sharing of objectives and meeting materials) to reignite engagement.
- c. Embrace varied approaches for engaging the stakeholder community.

 Engagement via outreach, collaboration, partnerships, discussions, and conference presentations provides AHRQ and the team with opportunities to introduce the CDS Connect project, systems, and tools to the healthcare community. It also helps spur contributions to the Repository and use of the Authoring Tool, increasing the likelihood of sustained use of the systems. Although there are more mechanisms for outreach than available resources, there is value in creating an agile outreach plan that covers an array of approaches.

Overall, lessons learned applicable to the broader CDS community include themes of transparency, standards, and engagement. The CDS community often cites challenges with implementation and assessment of the impact of CDS. The team actively seeks enhancements to CDS Connect that will promote implementation and use and pursues proactive efforts toward these ends. For example, efforts are underway to invite the user community to specifically

engage about their experience and process of implementation of an artifact. Actively working to promote a cycle of development tightly coupled with feedback may be beneficial to the broader CDS community.

4. Recommendations for the Next Year of CDS Connect

1. Growing trust in CDS Connect

a. **Apply and assess the prioritization framework.** The prioritization framework was designed to streamline future planning efforts on CDS Connect. The planned year 5 of CDS Connect will be an important opportunity to apply the framework and assess its long-term value for sustaining and growing CDS Connect.

2. Maintaining open-source, standards-based offerings

- a. **Update CDS Connect artifacts to FHIR R4.** As vendors move toward adoption for FHIR R4, they will need FHIR R4-based CDS artifacts. The team should update its own artifacts' CQL expressions to use the FHIR R4 model. This process should be undertaken concurrently with the annual review of evidence, value sets, and clinical logic.
- b. **Update CDS Connect tools to support CQL 1.5.** CQL 1.5 is the first "normative" release of CQL, indicating that core aspects of CQL are no longer trial use and should be considered stable. The CDS Authoring Tool and all CDS Connect open source tools should be updated to support at least the normative aspects of CQL 1.5. This will likely require updates to the open source cql-execution library that they all use as a dependency.
- c. Update the CDS Authoring Tool to allow additional logical expressivity. AHRQ should continue to seek user feedback and identify common logical constructs that the CDS Authoring Tool should support through user-friendly interfaces. This promotes using the CDS Authoring Tool in more use cases and reduces authors' needs to develop CQL external to the CDS Authoring Tool.
- d. Continue to align with open standards. Aligning with CPG-on-FHIR has helped to harmonize the CDS Connect tools and services with related efforts outside of the CDS Connect project. The team should continue to build on this work, including additional features such as importing and exporting content as CPG resources. The team should also continue to maintain situational awareness of other emerging standards to ensure that CDS Connect tools and services stay current.

3. Promoting CDS Connect through engagement with the CDS community

a. Monitor and adapt stakeholder outreach practices to continue what works and discontinue what does not. Presentations at conferences, webinars, and meetings are effective vehicles to introduce the CDS Connect mission and systems to new

stakeholders, identify new CDS contributors and users of shared CDS, and explore sustainability approaches for CDS Connect software and resources. The team should also pursue outreach efforts in alternate media formats (e.g., podcasts or videos) because of their initial promise as resource efficient and simple methods for tracking reach relative to conference networking.

b. Track the reach of CDS Connect in the healthcare community. The core of AHRQ's mission is getting evidence into practical use. To date, work for CDS Connect has focused on making it a robust resource. There is an opportunity to increase knowledge of whether and how CDS artifacts are used by better understanding CDS Connect's reach within the healthcare community. Among the techniques to consider are regular tracking of site statistics, inclusion of additional badges on CDS artifacts to invite community engagement, displaying the number of downloads for each artifact, automatically emailing the publishing organization lead when one of its artifacts is downloaded, and exploring the application of behavioral economics to assess the return on investment.

Overall, recommendations applicable to the broader CDS community include themes of alignment and use. Members of the CDS community have opportunities to work together in adopting common standards that promote collaboration and growth from existing work. Consistent use of standards can also facilitate understanding of the use—and ultimately the impact—of CDS. Homing in on the impact of CDS to improve quality in healthcare is key to realizing its promise to improve patient-centered care with evidence.

Acronyms

Term Definition

AHRQ Agency for Healthcare Research and Quality

a.k.a. Also Known As

AMIA American Medical Informatics Association

API Application Programming Interface

APR Apache Portable Runtime

ARIA Accessible Rich Internet Applications

ASCVD Atherosclerotic Cardiovascular Disease

CDC Centers for Disease Control and Prevention

CDS Clinical Decision Support

CMS Centers for Medicare & Medicaid Services

CPG Clinical Practice Guidelines

CPI Center for Program Integrity

CQL Clinical Quality Language

CVD Cardiovascular Disease

DKIM Domain Keys Identified Mail

DSTU Draft Standard for Trial Use

eCQM Electronic Clinical Quality Measure

ELM Expression Logical Model

FFRDC Federally Funded Research and Development Center

FHIR® Fast Healthcare Interoperability Resources

HL7® Health Level Seven

ICD-10 International Classification of Diseases-10

IG Implementation Guide

IT Information Technology

JAWS Job Access With Speech

MCBK Mobilizing Computable Biomedical Knowledge

OID Object Identifier

ONC Office of the National Coordinator for Health IT

Term Definition

PCCDS- Patient-Centered Clinical Decision Support Learning Network

LN

PCOR Patient-Centered Outcomes Research

R4 Reference 4

SMART Substitutable Medical Applications, Reusable Technologies

STU Standard for Trial Use

URI Universal Resource Identifier

URL Uniform Resource Locator

T&C Terms and Conditions

U.S.C. United States Code

VSAC Value Set Authority Center

WG Work Group